DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2006

WARNING LETTER

VIA FEDERAL EXPRESS

Mary Edwards
Global Vice President
Regulatory Affairs
Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403

Dear Ms. Edwards:

In accordance with section 522 of the Federal Food, Drug and Cosmetic Act (the Act) and 21 CFR Part 822, by order dated June 13, 2001, the Food and Drug Administration (FDA) ordered your firm to conduct postmarket surveillance for the AneuRx endovascular graft system for the treatment of Abdominal Aortic Aneurysm (AAA). Your postmarket surveillance plan for this device, originally approved April 26, 2002, requires submission of interim reports on this postmarket surveillance. Specifically, the approved plan, as modified by Medtronic's request of July 11, 2005, which FDA approved on August 9, 2005, required submission of interim reports annually beginning May 31, 2006. As of September 27, 2006, your firm has failed to submit the interim report for the AneuRx endovascular graft system that was due on May 31, 2006, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Failure to adhere to requirements under the Federal Food Drug and Cosmetic Act and the Code of Federal Regulations [21 USC 331(q)(1)- Prohibited Acts; 352(t)(3)- Misbranded Drugs and Devices and 21 CFR 822. 25(d); 822.28-Postmarket Surveillance]

Failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the Act (21 USC 331(q)(1)). Further, under section 502(t)(3) of the Act, a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the Act (21 USC 352(t)(3)). Under 21 CFR § 822.25(d), a manufacturer must ensure that any reports required as part of the approved postmarket surveillance plan are submitted to FDA in a timely manner, and under 21 CFR § 822.38, a manufacturer is required to submit interim and final reports as specified in the approved postmarket surveillance plan. Therefore, Medtronic has committed a prohibited act by failing to submit the required report on time, and its AneuRx devices are currently misbranded.

You should take prompt action to correct this violation. Failure to promptly correct this violation may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Please note that Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

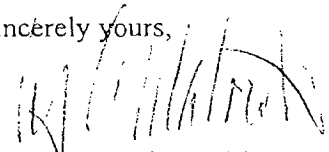
Within fifteen (15) calendar days from the date of this letter, please submit your interim report to the Postmarket Surveillance Document Center, HFZ-510, Center for Devices and Radiological Health, 9200 Corporate Boulevard, Rockville, MD 20850.

Also within fifteen (15) calendar days from the date of this letter, please notify the Center for Devices and Radiological Health (CDRH) in writing of the specific steps you have taken to correct this violation and ensure that this violation or similar violations do not occur again. Please include supporting documentation. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 calendar days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this letter should be sent to: Laura Alonge, Issues Management Staff, (HFZ-510), Office of Surveillance and Biometrics, Center for Devices and Radiological Health, 9200 Corporate Boulevard, Rockville, Maryland 20850 If you have any questions about the content of this letter please contact: Laura Alonge at 240-276-3365 (telephone) or 240-276-3356 (fax).

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of devices. This letter pertains only to the issue of postmarket surveillance reporting requirements for your device and does not necessarily address other obligations you have under the law.

Sincerely yours,



Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health